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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/081,953

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William J. Hennen

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Durham, Jones & Pinegar --
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EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

NOTIFICATION DATE

DELIVERY MODE

06/01/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/081,953	Applicant(s) HENNEN ET AL.	
	Examiner Stacy B. Chen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-22 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment and remarks filed on April 5, 2010 have been entered. Claims 1-16 and 18-23 are pending and under examination.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16 and 18-22 remain rejected under 35 U.S.C. 102(e) as being anticipated by Dopson (PGPub 2002/0044942A1, “Dopson”, published April 18, 2002, with priority to provisional application 60/233,400, filed September 18, 2000), for reasons of record. Applicant indicates in the response filed April 5, 2010, that an affidavit may be filed once all other issues in this application are resolved.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokoro (US Patent 5,080,895) in view of Kirkpatrick *et al.* (US Patent 5,840,700, "Kirkpatrick"), for reasons of record. Applicant's arguments have been carefully considered but fail to persuade. Applicant's arguments are directed to the following:

- Applicant notes that Tokoro teaches that the antigen used to immunize the hens is any substance to which the immune system of the animal will respond. Applicant argues that Tokoro does not teach or suggest that the immune response be specifically a T-cell response. Applicant notes that a T-cell response is critical to the production of transfer factor. Tokoro's hens were exposed to the specific bacterial antigens suggested by Tokoro, yet they did not have a T-cell response. Applicant notes that the specific antigens disclosed by Tokoro would not have caused chickens to elicit a T-cell response.
- In response to Applicant's arguments, the Office has previously acknowledged that certain bacterial antigens suggested by Tokoro, such as an ETEC antigen, are not expected to induce T-cell mediated immunity in hens. The Office also acknowledges that a T-cell response is critical to the production of transfer factor. However, Tokoro does not have to teach that the antigens elicit a T-cell response. The obviousness rejection relies on Tokoro's description of a transfer factor-like component that is specific for an antigen from a pathogen, in combination with a reference that teaches an antigen/pathogen that is known to induce T-cell mediated immunity in an animal.

Art Unit: 1648

- For example, Tokoro fails to disclose EBV-specific transfer factor. However, Tokoro suggests the use of virtually any antigen of choice for the production of a substance containing transfer factor-like component, including those other than intestinal infectious diseases (col. 4, lines 16-18). Antigens from pollen, bacteria, viruses, molds, allergens, blood from affected animals, sperm and toxins may be used in the production of transfer factor-like component (col. 4, lines 53-57). One would have been motivated to select an antigen from a clinically significant pathogen such as Epstein-Barr virus, a known pathogen for which a vaccine is desirable to prevent mononucleosis (Kirkpatrick, col. 5, lines 7-30). By immunizing hens with an EBV antigen, Tokoro's hens would have produced transfer factor-like component specific for EBV.
- Applicant argues that the "transfer factor-like component" produced as a result of Tokoro's method is distinct from Applicant's transfer factor. Applicant asserts that at the time of the Tokoro patent application filing date, transfer factor was known to be produced in a T cell-mediated immune response from leukocytes, lymphocytes or lymphoid cell sources (not eggs), and there was some understanding of its immunological functions. Applicant notes that Kirkpatrick teaches that transfer factors are extracted from lymphoid cells (not eggs). However, Applicant asserts that the immunological functions and other characteristics of Tokoro's "transfer factor-like component" were not known at that time.
- In response to Applicant's assertion that Tokoro's transfer factor-like component is distinct from Applicant's transfer factor, the Office has previously addressed

this concern. While Applicant is relying on what was known in the art at the time of the filing of the Tokoro patent application, and even what was disclosed in Kirkpatrick, the information regarding the known sources of transfer factor does not overrule Tokoro's teachings.

- Tokoro's composition comprising the transfer factor-like component is antibody-free, and contains molecules having a molecular weight of less than 10 kD (col. 5, lines 14-21). Thus, Tokoro recognizes that a) the transfer factor-like component is not an antibody, 2) that it has a lower molecular weight than antibodies, and 3) it is specific for the antigen used to immunize the hen from which the transfer factor-like component was produced. Tokoro suggests the use of virtually any antigen of choice for the production of a substance containing transfer factor-like component, including those other than intestinal infectious diseases (col. 4, lines 16-18). Antigens from pollen, bacteria, viruses, molds, allergens, blood from affected animals, sperm and toxins may be used in the production of transfer factor-like component (col. 4, lines 53-57).
- Therefore, given Tokoro's characterization of the transfer factor-like component, which matches Applicant's description of "transfer factor" (*i.e.*, transfer factors are structurally analogous to antibodies but smaller than 10 kD, see paragraphs [0010] and [0013] of the instant specification), it is expected that Tokoro's composition (in combination with Kirkpatrick's suggestion to use EBV antigen, for example) contains antigen-specific transfer factor.

Conclusion

4. No claim is allowed. Claim 23 is objected to as being dependent on a rejected claim.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/
Primary Examiner, TC1600